

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 1-10 and 19-24 are pending after entry of the amendments set forth herein.

Claims 1, 4-7 and 22 are amended for clarity. Support for these amendments is found throughout the specification, as well as in the claims as originally filed.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

**Rejections Under §112 ¶2**

Claim 1-10 and 19-24 were rejected under 35 USC 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicants respectfully traverse these rejections as applied and as they may be applied to the pending claims.

**Claim 1**

Claim 1 was rejected as being vague and indefinite in that the preamble of the claim did not match the end result of practicing the recited steps. More specifically the Examiner argues that if an agent inhibits NF- $\kappa$ B activity in vitro it may not necessary inhibit its activity in a cell.

It is important to note that the term “in vitro” as used in the specification refers to both cell-free and cell-based assays. For example, the specification describes cell-free “in vitro” assays in paragraphs [0072] – [0076], including cell-free in vitro transcription assays (see paragraph [0072]). The specification also describes cell-based “in vitro” assays at, for example, paragraphs [0077] – [0086]. The term “in vitro,” as it is employed in Claim 1 is generic to both cell-free and cell-based assays. Therefore the reasons cited by examiner (*e.g.*, inability to enter the cell, degradation in the cell, multiple effects in the cell, etc.), are readily addressed simply by use of a cell-based in vitro assay. as encompassed by Claim 1.

However, in the spirit of moving prosecution forward, Claim 1 is amended for clarification. Applicants note that claims 7 and 22, for example, encompass both cell-free and cell-based in vitro assays.

Applicants respectfully request that the rejection be withdrawn.

#### Claim 6

Claim 6 was rejected as being vague and indefinite. Specifically the Office Action states that the limitation in Claim 6 reciting the use of a eukaryotic cell environment is mutually exclusive with the method of Claim 1, which states that the candidate agent is contacted with RelA in an in vitro environment. The Examiner kindly suggested that this limitation be removed from Claim 6 to remedy the two mutually exclusive limitations.

As noted above, the term “in vitro” refers to both cell-free environment as well as a cell-based assays. Thus dependent claim 6 was within the scope of claim 1 as previously presented.

However, in order to clarify the language of the claims and to expedite prosecution, Claim 1 is amended to refer to cell-based assays, and Claim 6 is amended for clarity and conciseness.

In addition, the Office Action states that the limitation in Claim 6 reciting detection of deacetylated RelA by detection of an increase in RelA binding to I $\kappa$ B $\alpha$  is objectionable. The Office Action takes the position an increase in the association between deacetylated RelA with I $\kappa$ B $\alpha$  does not necessarily lead to the conclusion that the candidate agent affects the deacetylation of RelA.

Applicants respectfully disagree. As noted in specification paragraph [0088], RelA only binds I $\kappa$ B $\alpha$  if RelA is deacetylated. Binding of deacetylated RelA to I $\kappa$ B $\alpha$  promotes nuclear export of deacetylated RelA. Thus detection of binding of RelA to I $\kappa$ B $\alpha$  provides a means, albeit indirect, of detecting deacetylated RelA.

The Office Action further asserts that a compound that inhibits the dissociation of I $\kappa$ B $\alpha$  from RelA would also appear to be affecting RelA acetylation. However, Applicant would like to point out that the object of the described limitation is to seek a relative increase in the association between RelA and I $\kappa$ B $\alpha$ , not a decrease or static change, as suggested by the comment in the Office Action.

Withdrawal of the rejection of Claim 6 is respectfully requested.

**Claim 7**

Claim 7 was rejected as being vague and indefinite with respect to the comparison of deacetylated RelA between the two samples. As kindly suggested by the Examiner, Claim 7 has been amended to clarify that the comparison is between the levels of deacetylated RelA in the two samples.

This rejection can thus be withdrawn.

**Claim 22**

Claim 22 was rejected as being vague and indefinite for recitation of "HDAC2". As kindly suggested by Examiner, Claim 22 has been amended to remove the term "HDAC2 and replace it with the term HDAC3.

Withdrawal of this rejection is respectfully requested.

**Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-234.

Respectfully submitted,  
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Date: \_\_\_\_\_

Sept 8, 2003

By: \_\_\_\_\_

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